



0438
0300
PATENT #4

Attorney Docket No. 0180.0026

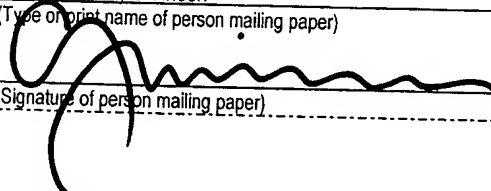
CERTIFICATION MAILING

I hereby certify that on March 8, 2002 this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231.

37 CFR 1.8(a)
☒ with sufficient postage as first class mail

37 CFR 1.10
☐ as "Express Mail Post Office to Addressee" Mailing Label No. _____

Gayle Vinson
(Type or print name of person mailing paper)


(Signature of person mailing paper)

Serial No. 10/051,652
Filed: January 15, 2002
Title: ANTIBODY-AVIDIN FUSION PROTEINS AS CYTOTOXIC DRUGS
Applicant: Penichet et al.
Group Art Unit No. n/a
Examiner: n/a

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner of Patents
Washington, D.C. 20231

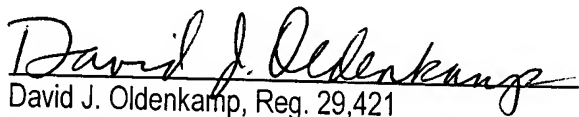
INFORMATION DISCLOSURE STATEMENT

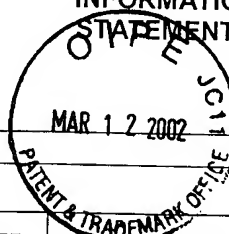
Sir:

In recognition of the duty to disclose all relevant and material information of which they are aware, applicants direct the Examiner's attention to the references listed on the attached PTO Form 1449. A copy of each listed reference is enclosed.

Dated: March 8, 2002

Respectfully submitted,


David J. Oldenkamp, Reg. 29,421
SHAPIRO & DUPONT LLP
233 Wilshire Boulevard, Suite 700
Santa Monica, California 90401
(310) 319-5411 (Telephone)
(310) 319-5401 (Facsimile)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY DOCKET NO.
0180.0026SERIAL NO.
10/051,652INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANTS
PENICHER ET AL.FILING DATE
JANUARY 15, 2002GROUP
N/A

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,672,683	09-30-97	Friden et al.	530	350	07-16-93
	5,807,715	09-15-98	Morrison et al.	435	69.6	06-27-94
	6,287,792	09-11-01	Pardridge et al.	435	7.5	06-17-91

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
WO 01/07084 A1	01.02.2001	PCT	A61K	39/44	X	

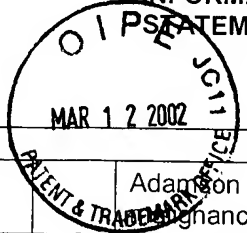
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Shin SU, Wu D, Ramanathan R, Pardridge WM, and Morrison SL. Functional and pharmacokinetic properties of antibody-avidin fusion properties. J Immunol. 1997, 158 (10):4797-804.
	Jeffried WA, Brandon MR, Williams AF, Hunt SV. Analysis of lymphopoietic stem cells with a monoclonal antibody to the rat transferrin receptor. Immunology. 1985, 54:331-341.
	Penichet ML, Kang YS, Pardridge WM, Morrison SL, Shin SU. An antibody-avidin fusion protein specific for the transferrin receptor serves as a delivery vehicle for effective brain targeting: initial applications in anti-HIV antisense drug delivery to the brain. J. Immunol. 1999, 163:4421-4426.
	Galfr G, Milstein C, Wright B. Rat x rat hybrid myelomas and a monoclonal anti-Fd portion of mouse IgG. Nature 1979, 277:131-133.
	Van Engeland M, Nieland LJ, Ramaekers FC, Schutte B, Reutelingsperger, CP. Annexin V-affinity assay: a review on an apoptosis detection system based on phosphatidylserine exposure. Cytometry 1998, 31:1-9.
	Arends MJ, Morris RG, Wyllie AH. Apoptosis. The role of the endonuclease. Am. J. Pathol. 1990, 136:593-608.
	Friden PM, Olson TS, Obar R, Walus LR, and Putney SD. Characterization, receptor mapping and blood-brain barrier transcytosis of antibodies to the human transferrin receptor. J. Pharmacol. Exp. Ther. 1996, 278:1491-8.
	Kearney JF, Radbruch A, Liesegang B, and Rajewsky K. A new mouse myeloma cell line that has lost immunoglobulin expression but permits the construction of antibody-secreting hybrid cell lines. J. Immunol. 1979, 123:1548-50.
	Andersson LC, Nilsson K, and Gahmberg CG. K562--a human erythroleukemic cell line. Int. J. Cancer. 1979, 23:143-7.
	Green NM. <i>Advances in Protein Chemistry</i> , Vol. 29, pp. 85-133, 1975.
	Kaplan, II. <i>American Journal of Medical Science</i> , Vol. 207, pp. 733-743, 1944.
	Gope ML et al. <i>Nucleic Acids Research</i> , Vol. 15, pp.3595-3606, 1987.
	Kang YS and Pardridge WM. Use of Neutral Avidin Improves Pharmacokinetics and Brain Delivery of Biotin Bound to an Avidin-Monoclonal Antibody Conjugate. J. Pharmacology and Experimental Therapeutics, Vol. 29, pp. 344-350, 1994.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT 	ATTY DOCKET NO. 0180.0026	SERIAL NO. 10/051,652
	APPLICANTS PENICHER ET AL.	
	FILING DATE JANUARY 15, 2002	GROUP N/A

	Adamson PJ, Zola H, Nicholson IC, Pilkington G, Hohmann A. Antibody against CD20 in patients with B cell malignancy. <i>Leuk Res.</i> 2001, 25: 1047-50.
	Barth S. hIL-13-PE38QQR. <i>NeoPharm. Curr Opin Investig Drugs.</i> 2001, 2:1309-13.
	Brooks D, Taylor C, Dos Santos B, Linden H, Houghton A, Hecht TT, Kornfeld S, Taetle R. Phase Ia trial of murine immunoglobulin A antitransferrin receptor antibody 42/6. <i>Clin Cancer Res.</i> 1995, 1: 1259-65.
	Habelshaw, H. A., Lister, T. A., and Stansfeld, A. G.s. Correlation of transferrin receptor expression with histological class and outcome in non-Hodgkin lymphoma. <i>Lancet.</i> 1983, 1: 498-500.
	Hall WA. Targeted toxin therapy for malignant astrocytoma. <i>Neurosurgery.</i> 2000, 46: 544-51.
	Laske DW, Youle RJ, Oldfield EH. Tumor regression with regional distribution of the targeted toxin TF-CRM107 in patients with malignant brain tumors. <i>Nat Med.</i> 1997, 3:1362-8.
	Leng J, Lang J, Shen K, Guo L. Overexpression of p53, EGFR, c-erbB2 and c-erbB3 in endometrioid carcinoma of the ovary. <i>Chin Med Sci J.</i> 1997, 12: 67-70.
	Li JY, Sugimura K, Boado RJ, Lee HJ, Zhang C, Duebel S, Pardridge WM. Genetically engineered brain drug delivery vectors: cloning, expression and <i>in vivo</i> application of an anti-transferrin receptor single chain antibody-streptavidin fusion gene and protein. <i>Protein Eng</i> 1999, 12:787-96.
	Livingston RB, Esteva FJ. Chemotherapy and herceptin for HER2(+) metastatic breast cancer: the best drug? <i>Oncologist.</i> 2001, 6: 315-6.
	Manzke O, Russello O, Leenen C, Diehl V, Bohlen H, Berthold F. Immunotherapeutic strategies in neuroblastoma: antitumoral activity of deglycosylated Ricin A conjugated anti-GD2 antibodies and anti-CD3xanti-GD2 bispecific antibodies. <i>Med Pediatr Oncol.</i> 2001, 36:185-9.
	Marttila AT, Laitinen OH, Airenne KJ, Kulik T, Bayer EA, Wilchek M, Kulomaa MS. Recombinant NeutraLite avidin: a non-glycosylated, acidic mutant of chicken avidin that exhibits high affinity for biotin and low non-specific binding properties. <i>FEBS Lett.</i> 2000, 467: 31-6.
	Mayers, GL, Razeq, J, and Abu-Hadid, MM. Cytotoxic drug conjugates for treatment of neoplastic disease. <i>US Patent Application No. 5,393,737.</i> 1995.
	Mayers, GL, Raghavan, D, Hitt, S, and Graves, D. Transferrin-Gemcitabine conjugates: application to chemotherapy. <i>In Proceedings of the 89th Annual Meeting of the American Association for Cancer Research, New Orleans, Louisiana, USA, March 28-April 1, 1998.</i> p 63. 1998.
	Meyer DL, Schultz J, Lin Y, Henry A, Sanderson J, Jackson JM, Goshorn S, Rees AR, Graves SS. Reduced antibody response to streptavidin through site-directed mutagenesis. <i>Protein Sci.</i> 2001, 10: 491-503.
	Nichols J, Foss F, Kuzel TM, LeMaistre CF, Platanius L, Ratain MJ, Rook A, Saleh M, and Schwartz G. Interleukin-2 fusion protein: an investigational therapy for interleukin-2 receptor expressing malignancies. <i>Eur. J. Cancer.</i> 1997, 33 Suppl 1: S34-36.
	Penichet ML, Kang YS, Pardridge WM, Morrison SL, Shin SU. An antibody-avidin fusion protein specific for the transferrin receptor serves as a delivery vehicle for effective brain targeting: initial applications in anti-HIV antisense drug delivery to the brain. <i>J Immunol.</i> 1999a, 163: 4421-6.
	Penichet ML, Shin SU, and Morrison SL. Fab fusion proteins: Immunoligands. <i>In Antibody Fusion Proteins.</i> Chamow S.M. and A. Ashkenazi, eds. John Wiley & Son, Inc., New York. 1999b. pp. 15-52.
	Penichet ML and Morrison SL. Antibody Engineering. <i>In Encyclopedia of Molecular Medicine (EMM).</i> Thomas E. Creighton, ed. John Wiley & Son, Inc., New York, 2001. Volume 1, pp. 214 to 216.

EXAMINER	DATE CONSIDERED
-----------------	------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE**
ATTY DOCKET NO.
0180.0026

SERIAL NO.
10/051,652

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
APPLICANTS
PENICHET ET AL.

FILING DATE
JANUARY 15, 2002

GROUP
N/A

MAR 12 2002

Jost AC, Menegaux F, Langlois P, Vidal JM, Koulibaly M, Jost JL, Duron JJ, Chigot JP, Vayre P, Aurengo A, Legrand JC, Rosselin G, Gespach C. Differential transferrin receptor density in human colorectal cancer: A potential probe for diagnosis and therapy. *Int J Oncol.* 1998, 13: 871-5.

Psarras, K., Ueda, M., Yamamura, T., Ozawa, S., Kitajima, M., Aiso, S., Komatsu, S., and Seno, M.s. Human pancreatic RNase1-human epidermal growth factor fusion: an entirely human 'immunotoxin analog' with cytotoxic properties against squamous cellcarcinomas. *Protein Eng.* 1998, 11: 1285-92.

Rybak, S. M., Saxena, S. K., Ackerman, E. J., and Youle, R. J.s. Cytotoxic potential of ribonuclease and ribonuclease hybrid proteins. *J. Biol. Chem.* 1991, 266: 21202-7.

Shinohara H, Fan D, Ozawa S, Yano S, Van Arsdell M, Viner JL, Beers R, Pastan I, Fidler IJ. Site-specific expression of transferrin receptor by human colon cancer cells directly correlates with eradication by antitransferrin recombinant immunotoxin. *Int J Oncol.* 2000, 17: 643-51.

Strauchen, J. A. and Breakstone, B. A.s. IL-2 receptor expression in human lymphoid lesions. Immunohistochemical study of 166 cases. *Am. J. Pathol.* 1987, 126: 506-512

Sweeney EB and Murphy J. R. Diphtheria toxin-based receptor-specific chimaeric toxins as targeted therapies. *Essays Biochem.* 1995, 30: 119-31.

Singh M, Atwal H, Micetich R. Transferrin directed delivery of adriamycin to human cells. *Anticancer Res* 1998, 18: 1423-1427.

EXAMINER
DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.